

REMARKS

This amendment is responsive to the Final Office Action dated January 29, 2004. Reconsideration is respectfully requested in view of the foregoing amendments. These remarks follow the order of the outstanding Office Action beginning at page 2 thereof.

Claim Rejections - 35 USC § 112

Claims 1, 2 and 7 have been amended to place them in the condition they were in prior to December 30, 2003. And in the condition they were in upon issuance of the first Office Action. The term "mobile" has been changed back to "fluid". Applicant has made this change not on the premise that the specification fails to teach "mobile", but on the Examiner's contention that "mobile" means "capable of being moved place to place" and that the indicators in the cited references would then be mobile. This Applicant also asserts is a strained interpretation of the term "mobile". Movement from place to place occurs with every object in the universe, as explained by Einstein. The Examiner's desk appears to be stationary, but with the Examiner's interpretation of "mobile" it is clearly moving as the surface of the earth, and the sun, and the earth about the sun.

Dictionary definitions are always referred to in interpreting patent specification and claims, see Markman v. West View Inst 34 USPQ 2d 1321 and the host of cases which cite Markman.

Applicant respectfully submits that the term "mobile" means capable of moving or being moved from one place to another (see, dictionary definition #1). According to the definition, found in definition 1, mobility is also described as "characterized by an extreme degree of fluidity" (i.e., liquids). Applicant claimed the liquid the first time and has reverted to the liquid definition of the invention. However, Applicant asserts that the meaning is the same.

Mobility is also described as the average speed with which molecules in solution diffuse under influence of a unit of osmotic pressure gradient (see dictionary definition #2).

Dictionary definition #2a defines "mobile" as capable of being moved. Here the '060 reference uses the words nonmotile to describe ions fixed on the membrane. Applicant has ions in a fluid which are by definition mobile.

In dictionary definition #3, the word "mobile" is used to describe a printing ink that tends to flow freely. This is obviously in reference to a fluid ink. The word "flow" would refer to fluid. This same dictionary also defines "mobility" in terms of "the degree to which a material is able to flow". Applicant's original specification and original claims all refer to fluid and it is well known that fluids flow.

Dictionary definition #4 shows that a fluid can be a liquid.

In Applicant's claim 1, Applicant claimed a fluid indicator. Dictionary definition #5 shows a definition of indicator, and that

it may be a color change in the condition of a solution. Solution can be considered to be a fluid, see dictionary definition #5.

In dictionary definition #6, fluid is defined as relating to a fluid and having the characteristics of a fluid. Dictionary definition #6 also shows that the term "fluidal" relates to or is characteristic of a fluid or flowing motion. Motion is clearly the same as mobile.

Dictionary definition #7 relates to the term "indicator". This term is used in Applicant's claims 1 and 2 in combination with the word "fluid" to make up the word combination "fluid indicator". Note, the "indicator" referred to in claim 7 is not prefaced by "fluid".

The definition of dictionary definition #7 refers the reader to "Reactions Involving Recombinations of Ions".

Dictionary definition #8 describes reactions which involve recombination of ions. Here, various reactions are described where the ions are in water (see Example 1 for the ionic equations including the presence water).

The above definitions and information on Reactions Involving Recombinations of Ions establishes beyond any doubt that the ions within water are mobile within the water. Stated another way, it is beyond any doubt that ions provide a fluid indicator where the ionic materials which are the indicator have mobility within the fluid.

Applicant's claims, therefore, as originally presented requiring that there be a fluid indicator portion recite mobility as later claimed.

Claim 1

Claim 1 has been rejected under 35 USC § 102(b) as being anticipated by Turner '060 as stated in the Office Action dated September 9, 2003. This is the rejection incorporated into the Final Office Action dated January 29, 2004. Applicant respectfully traverses this rejection on the grounds that Applicant's claim 1 as presented when rejected on September 9, 2003 (and now as presented) claims a fluid indicator isolated from the medium portion. Turner '060 while isolating his membrane from the microorganism culture with a gas-permeable, ion-impermeable membrane, as described at column 4, lines 19 - 29, does not anticipate Applicant's claim because Applicant claims the "fluid". The Examiner in the rejection on September 9, 2003, at the bottom of page 2, did not address this point at all.

However, the Examiner then at the top of page 4 attempted to rectify the failure of Turner to teach a fluid indicator portion. The Examiner argues here that Turner does not limit the selection of indicator. However, a fluid is not disclosed in Turner.

Although there is no 35 USC § 103 rejection of claim 1, the Examiner further argues no criticality at this portion of the

Office Action. This reasoning is respectfully traversed. Turner '060 consistently teaches that the sensor is a support medium to which a pH indicator can be covalently attached using organic reactions. Also, non-covalent attachment of pH indicators is suggested by using ionic support materials, such as nylon membranes that have a positive or negative zeta potential (see column 4, lines 62 - 66). '060 in column 3, lines 40 - 45 teaches that the sensor must be a solid composition or membrane which is referred to as an attachment or support medium, with an indicator medium immobilized on it. This is simply not a fluid. The reference to indicators found in column 4, lines 55 - 61, includes various indicators. Yet it does not state that these are in a fluid condition where they are allowed to be mobile.

'060 teaches that the indicator membranes may be used directly in the solution containing the reacting materials. This is the reason that the indicators must be fixed to the indicator medium (immobilized on or within it) (see column 3, lines 40 - 45). The membrane may be in direct contact with the microbial growth medium (column 5, lines 3 - 5). The indicator of '060 simply does not meet the limitation in claim 1 that the indicator must be a fluid indicator.

If the Examiner asserts that '060 has an indicator in contact with a fluid (which has to be the fluid of the growth medium), then the terms of claim 1 are not met because Applicant requires that the fluid indicator be isolated from the medium portion. If,

on the other hand, the Examiner asserts that the indicator membrane with the immobilized medium is separated from the culture by the gas-permeable, ion-impermeable membrane, (column 4, lines 20 - 22), then '060 fails to meet the limitations of claim 1 because the indicator can no longer be in contact with the fluid.

Claim 1 DiGuisseppi '769

Claim 1 has been rejected under 35 USC § 102(e) as being anticipated by '769 as stated in the Office Action dated September 9, 2003, page 3. Here, again, the Examiner relies upon the feature that the membrane permits the passage of gas, but prevents the passage of ions. However, Applicant asserts that the membrane taught in '769 is no different than the membrane taught in '060. In '769, the medium is mobilized on or within the membrane (see column 1, lines 20 - 42). This is not placement of the indicator portion in a fluid as claimed along with the claim separation. All '769 does is separate the membrane from the fluid or place it in the fluid. There is never any teaching of a fluid indicator which is separated by the membrane.

At the top of page 4, the Examiner refers to claim 1 of DiGuisseppi '769 and states that DiGuisseppi does not limit the state of the indicator. This position by the Examiner is respectfully traversed. '769 at column 1, lines 20 - 22, incorporates by reference the '060 patent which teaches that the

sensor has the medium immobilized (see also column 5, lines 20 - 42 of '769).

The Examiner relies upon claim 1 of DiGuisseppi as not limiting the state of the indicator. Claim 1 of '769, however, recites a container having at least one transparent section and a sterilizable indicator located in the container in the region of a transparent section. This does not isolate the indicator portion from the medium portion by a CO₂ gas-permeable membrane as claimed in claim 1. Next, '769, as pointed out above, teaches that the indicator indicates a change in properties. However, the indicator taught is where the indicator component is immobile on the support medium. The purpose of this is to prevent interaction with the culture medium during growth. There is simply nothing in this claim that suggests or teaches that the state of the indicator can be anything other than what is taught in the patent which is an indicator which an immobilized medium.

Applicant previously discussed dictionary definition #8 which describes a typical indicator located in a container (fluid) which may also contain a culture. Simply stated, neither '769 nor dictionary definition #8 suggest Applicant's invention which is use of the membrane to isolate the fluid indicator portion from the medium portion as set forth in clause (b) of claim 1.

Next, at the top of page 4, the Examiner argues "no criticality is seen in the state of the indicator". By this, it is presumed that the Examiner is referring to the physical state

of the indicator and whether or not it is in a fluid state or whether it is immobilized on or within the solid composition or membrane as taught by '060 and '769. There is no 35 USC § 103 rejection of claim 1.

At the bottom of page 3 (Office Action dated September 9, 2003), the Examiner states that Applicant argues that the references do not teach what the state of the sensor material is. Applicant disagrees. At the time this was written, Applicant asserted that '060 teaches autoclave type materials (paper filed April 4, 2003, bottom of page 7). The issue of what the sensor material is (if the Examiner is referring to the actual sensing indicators as described in '060, lines 57 - 61) is simply not at issue. Applicant has not claimed specific indicators.

The Examiner in arguing that no criticality (an irrelevant 35 USC § 103 legal argument) is seen in the state of the indicator, is avoiding the fact that Applicant has clearly claimed a physical difference, namely a fluid indicator, not the membrane with indicator medium immobilized on or within it as '060 teaches. Normally, criticality is a doctrine that relates to claiming of ranges and unexpected results (see MPEP § 2144.05 and In re: Woodruf 16 USPQ 2d 1934 (Fed. Cir. 1990). MPEP § 716.02 - 716.02(g) also relates to unexpected results and ranges. None of this applies to Applicant's invention when Applicant's invention is compared to the '060 prior art. Applicant's invention is for a physical structure which is entirely different from '060.

Applicant uses a fluid, '060 uses a solid composition or membrane with an indicator or medium immobilized upon it. The reason for Applicant's structure is that Applicant has shown in Applicant's Figure 2 shines the light through the medium in order to perform detection. On the other hand, '060 bounces the light off of the sensor (2) as shown in Figure 1. The physical devices are different, and this explains the difference in the type of sensor claimed.

As pointed out in MPEP § 2144.05, a prima facie case of obviousness (which the Examiner has not even asserted here), may be rebuttaled by showing that the art teaches away from the claimed invention. Here, Applicant respectfully submits that '060 clearly teaches away from Applicant's claimed invention which is the use of the fluid indicator as opposed to the solid composition or membrane with indicator immobilized on or within it. The physical structure and the physical use of the sensor of '060 suggests an entirely different way of measuring which is bouncing the light off the sensor, not passing the light through the sensor. This is a clear teaching away from Applicant's invention.

Claim 2

In the rejection of claim 2, appearing at the bottom of page 4 of the Office Action dated September 9, 2003, the Examiner acknowledges that the detection is with a fluid indicator and then argues in the line up from the bottom that the indicator may be

any state. The Examiner has not in this rejection stated why it would be obvious to one of ordinary skill in the art to abandon the solid composition or membrane sensor having an indicator medium immobilized on or within it and replace it with the fluid indicator. The Examiner refers to the "state indicator". The invention, however, is precisely the state of the indicator which is the use of the fluid indicator in combination with isolation from the medium portion by a CO₂-gas-permeable membrane.

None of the references taken singly or in combination teach or suggest that the sensor of '060 may be ignored and a fluid indicator substituted for it.

'060 not only fails to suggest the use of a liquid indicator, it teaches away from use of the liquid indicator as claimed at column 4, line 6. Here '060 states that there be a high concentration of indicator molecules maintained within a small volume on the membrane such that color change can easily be observed. This is clearly not the case in a liquid indicator where light must pass through, and not bounce off of the indicator as taught in '060. For this reason '060 teaches away from the claimed invention, and certainly does not suggest the use of a liquid in place of the disclosed sensor or membrane.

Claims 2 and 7 - 35 USC § 103(a)

Claim 1 is not rejected under 35 USC § 103.

Claims 2 and 7 each in elements (e) and (f) (which are identical) set forth a first step of measuring time starting from when said container is sealed unto a moment when color of said CO₂ indicator is turned to a predetermined color and (f) identifying initial quantities of microorganism obtained by comparing measured time against contents of a table which hold precollected time data on each microorganism species of known initial quantities in known amount of sample.

It is respectfully submitted that the Office Action dated September 9, 2003, at pages 4 and 5 do not address the question of identifying initial quantities. The term "initial" does not appear in the Examiner's discussion, nor does it appear in the reference. Still further, the references and the Examiner's discussion of them does not at all deal with tables which are prepared in advance and which hold precollected time data on each microorganism species of known initial quantities in known amount of sample.

The amount of sample and initial quantities of the known amount of sample. The references lacking these claimed elements simply do not suggest Applicant's claimed method. For the foregoing reason, the rejection under 35 USC § 103 is respectfully traversed.

In view of the foregoing, it is respectfully submitted that the application is now in condition for allowance, and early

S/N: 09/897,105

3/29/2004

DOCKET NO.: SUDA-109-DIV

action in accordance thereof is requested. In the event there is any reason why the application cannot be allowed in this current condition, it is respectfully requested that the Examiner contact the undersigned at the number listed below to resolve any problems by Interview or Examiner's Amendment.

Respectfully submitted,



Ronald R. Snider
Reg. No. 24,962

Date: March 29, 2004

Snider & Associates
Ronald R. Snider
P.O. Box 27613
Washington, D.C. 20038-7613
(202) 347-2600

RRS/bam